

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS:	DUNFEE, Albert H. et al.	CONF. NO.	9958
SERIAL NO.:	10/713,503	GROUP NO.:	3734
FILING DATE:	November 14, 2003	EXAMINER:	TRUONG, Kevin Thao
TITLE:	INTRALUMINAL CATHETER WITH HYDRAULICALLY COLLAPSIBLE SELF-EXPANDING PROTECTIVE DEVICE		

MAIL STOP AMENDMENT
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF BRUCE FLIGHT
UNDER 37 C.F.R. §1.132

The undersigned, Bruce Flight, declares as follows:

1. I am a senior engineer employed at Medtronic Vascular, Inc. in Danvers, Massachusetts. I have been employed as an engineer in the medical device field for twenty-eight years. I have designed, developed and participated in the manufacture of a variety of medical devices including catheters, guidewires, stents, endovascular filters and related equipment and devices, including syringes. I hold several patents relating to such technology. I am familiar with the components and materials from which catheters, guidewires, syringes and the like are manufactured and am familiar with medical procedures in which they are used.
2. Over the course of my career I have trained individuals with a wide spectrum of experience from neophyte engineers just entering the medical device field to physicians learning to use new devices and techniques. I am familiar with the levels of skills of

those involved in the design, development and manufacture of medical devices including catheters, guidewires and syringes.

3. One of ordinary skill in the art of catheters, guidewires, syringes and related devices would be expected to have at least a bachelor's degree in a relevant technology or equivalent experience as an engineer or technician. The individual would be expected to have become familiar with catheters, guidewires and syringes and their relationships and functions. The individual also would be expected to have a familiarity with human anatomy and physiology sufficient to understand the various environments in which a particular catheter, guidewire, syringe, or other device is intended to perform.
4. In particular, one of ordinary skill in the art of such devices and techniques would understand the fundamental relationship of a guidewire and a catheter, namely, that the purpose of a guidewire is to guide a catheter to an intended internal location in a patient, often, but not necessarily, through the patient's vasculature. One of ordinary skill in the art, indeed one of less than ordinary skill in the art, would be expected to understand that the diameter of a guidewire is selected to enable the catheter to be mounted on and to slide over and along the guidewire. It would not rise to the level of ordinary skill for one to understand that the guidewire must be dimensioned with respect to the guidewire lumen in the catheter to permit these components to perform their common function. In my opinion this would be recognized even by someone with less than ordinary skill.
5. Catheters and guidewires may be made from a variety of materials including polymeric as well as metallic components. Among the components commonly used in a variety of medical devices is a metallic tube commonly referred to as "hypotubing". Hypotubes are common elements in the manufacture and use of catheters, guidewires and other medical products and are used routinely as a construction component. Typically, hypotubes are seamless, have an internal lumen and are of relatively small diameters depending on the desired variables of flexibility, lumen size, and other factors. They are commercially available from a number of sources such as Creganna Medical Devices (www.creganna.com) and Popper & Sons, Inc. (www.popperandsons.com).

6. I have read U.S. patent 3,952,747 to Kimmell. That patent discloses a delivery catheter for a releasable vena cava filter that is carried on the distal end of the catheter. The filter is released by a mechanism responsive to an increased fluid pressure transmitted through the catheter. The pressure is generated by a syringe 48 attached to the proximal end of the catheter.
7. I have read and am familiar with U.S. patent application 10/713,503 filed November 14, 2003 as well as the claims, as amended. I also have read and am familiar with the official action of January 11, 2008.
8. A syringe and a hypotube are completely separate items having completely different functions and purposes. One of ordinary skill in the art would not consider a syringe to be a hypotube nor would one consider a hypotube to be a syringe. In my opinion, one of ordinary skill in the art would not consider characterization of a syringe, such as the syringe 48 in Kimmell to be a "hypotube". Considering the syringe 48 as being a hypotube is unreasonable. Catheter shaft 22 in Kimmell is not a hypotube and syringe 48 certainly is not a hypotube. I know of no device in which a catheter is passed over a syringe.
9. I have considered whether one of ordinary skill would, from a reading of the disclosure of application serial no. 10/713,503 recognize that the inventor had "possession" of the subject matter of claim 1 and, particularly, the claimed guidewire. As I understand it, "possession" is shown if the written description describes the invention, with all its claimed limitations. One of ordinary skill in the art clearly would have found such description present. Because of the inherent relationship between a guidewire (whether formed from a hypotube or any other construction) and a catheter, one of ordinary skill, indeed of subsidiary skill, would have recognized the inherent characteristic that the hypotube guidewire inherently must have an outer dimension to enable a therapeutic catheter to be advanced onto and along the guidewire.
10. I am equally of the opinion that the written description clearly describes the invention, and particularly the relationship between the diameter of the hypotube guidewire and its

relation to the catheter so that one skilled in the art would be able to make and use the invention.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

5/5/08

Date

Bruce W. Flight

Bruce Flight